



SEP 3 0 2005

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

SonoScape, Inc. % Mr. Bob Leiker Quality & Regulatory Services 7263 Cronin Circle DUBLIN CA 94568

Re: K052042

Trade Name: SonoScape SSI-1000/SSI-5000™

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: July 25, 2005 Received: July 28, 2005

#### Dear Mr. Leiker:

This letter corrects our substantially equivalent letter of August 9, 2005 regarding a wrong transducer number.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SonoScape SSI-1000/SSI-5000<sup>TM</sup>, as described in your premarket notification:

Transducer Model Number

2P1, PA2.5 MHz Phased Array L741, LA7.5 MHz Linear Array

C344, CLA3.5 MHz Curved Linear Array

MPTEE, 7-4 MHz/10mm/64 element Multi-Plane Transesophageal Phased Array

5P1, 7-4 MHz/10mm/64 element Phased Array

C611, 8-4 MHz/R11mm/128 element Micro-convex Array

6V1, 8-4 MHz/R11mm/128 element Transvaginal Micro-convex Array

10L1, 12-5 MHz/38mm/128 element Flat Linear Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

Diag	jno	Stic	υ	itrasc	ouna	System	indication	s for U	se	
510(k) Number:			_							
	stic	Ult	rasc	ound P	ulsed f	Echo Sys	stem maging Syste	m		
Intended Use: Diagno follows:	stic	ultr	raso	und in		or fluid fl of Operation	-	f the hum	nan body as	i
Clinical Application	Α	В	М	PWD	CWD		Power	Color Velocity Imaging	Combined	Tissue Harmon Imagin
Opthalmic										
Fetal										
Abdominal		₽	Ρ	P		P	P		Note 1	N
Ob/GYN		P	P	Р		P	Р		Note 1	N
IntraOperative Neurological										
Pediatric		N	N	N	N	N	N		Note 1	N
Small Organ (breast, thyroid, testes) Neonatal Cephalic		Р	P	Р	_	P	Р		Note 1	N
Adult Cephalic	-	$\vdash$	_							
Cardiac	$\vdash$	P	P	P	P	P	P	<del> </del> -	Note 1	N
Transesophageal		N	N	N	N	N	N		Note 1	N
Trans-Rectal	1	N	N	N		N	N	<del> </del>	Note 1	N
Trans-Vaginal	$\vdash$	N	N	N		N	N		Note 1	N
Trans-Urethral										
Intra-Vascular	-	-								
Peripheral Vascular		P	P	Р		P	Р		Note 1	N
Laparascopic	-	┢	一	<u> </u>	1	<u> </u>				<u> </u>
Muscular-Skeletal Conventional		P	Р	Р		P	Р		Note 1	N
Muscular-Skeletal Superficial										
Others (Specify)										
Note 1: Combined includ B/Power Dopple	les: E r/PW	B/M;					added under Ap 3/Power Doppler		Doppler/PWD	and
Additional Comments	í: 									
				Сенсинч	mor of CDR		Naucy Sign-Off)	Cbrog	don	
Prescription Use (Per 21 G Section 4.3	CFR	801.	.109)	) In	dications		n Sign-Off) of Reproductiv Intograal Devic Iumber _K.C			o
							-	_	' 2	

Prescription Use (Per 21 CFR 801.109)

510(k) Number:			-							
Device Name: 2P1, P Diagno										
Intended Use: Diagno follows:	stic	: ultı	rasc	ound in		or fluid fl	·	of the hum	ıan body as	;
Clinical Application	Α	В	М	PWD	CWD		Power	Color Velocity Imaging	1	Tissue Harmonic Imaging
Opthalmic										
Fetal						1				
Abdominal										
Ob/GYN										
IntraOperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)										
Neonatal Cephalic			_			<u> </u>		<b></b>		
Adult Cephalic	_		_						A1 4 4	
Cardiac		Р	Р	Р	Р	Р	Р		Note 1	Р
Transesophageal						ļ				
Trans-Rectal						<u> </u>				
Trans-Vaginal				<u> </u>		ļ				
Trans-Urethral			<u>L</u>					ļ		
Intra-Vascular					<u> </u>	<u> </u>				
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal						1				
Conventional					<b> </b>	<u> </u>				
Muscular-Skeletal Superficial										
Others (Specify)				l	<del> </del>	<del> </del>				
N = new indication P Note 1: Combined includ B/Power Doppler Additional Comments	les: E r/PW	3/M;	•		•		•	•	ppler/PWD an	ıd
							,	·····		
				Concurre	nce of CDR	III, Office of Dev	ice Evaluation (ODE)			
					on Sig	Nan	ey Cbroat	loz		
Prescription Use (Per 21 C	FR	<b>8</b> 01.	109)			opioanoni	v. choodining			
Section 4.3				510/kg	aciolog P <b>iratian</b> s	For Use	*K052	5.42	, Page 3 of 10	)

Dia	<i>3</i> 110	Sti		ili as	Juila	Cyston	maioatioi	13 101 0	30	
510(k) Number:			-							
Device Name: L741, Diagno										
Intended Use: Diagno follows:	ostic	uit	rasc	ound in	naging	or fluid fl	ow analysis o	of the hum	ıan body as	;
						of Operation	0ศ			
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	•	Tissue Harmonio Imaging
Opthalmic										
Fetal										
Abdominal						1				
Ob/GYN		_								
IntraOperative Neurological										
Pediatric	_		_							
Small Organ (breast, thyroid, testes)		P	Ρ	P		Р	P		Note 1	Р
Neonatal Cephalic	_	<u> </u>	_							
Adult Cephalic										
Cardiac	_	_								
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular		Г								
Peripheral Vascular		Р	Р	P		Р	Р		Note 1	Р
Laparascopic	Г	1								
Muscular-Skeletal		P	P	P	ļ —	Р	Р		Note 1	P
Conventional										
Muscular-Skeletal	Г	Г								
Superficial										
Others (Specify)										
N = new indication P Note 1: Combined includ B/Power Dopple Additional Comments	les: E r/PW	3/M;					idded under Ap i/Power Doppler		Doppler/PWD	and
, idailatiai commissia	•				•					
			C		rnou na	ce of Device Ev				
			Cook	mercalot de		_	Manage	broad	or	
						Division S Division of	Reproductive,	Abdomina	ęl <sub>.</sub>	
Prescription Use (Per 21 (	CFR	801.	109)	)	•	510(k) Nu	logical Devices	5204	2	

Section 4.3

Indications For Use

Page 4 of 10

510(k) Number:			-							
Device Name: C344, Diagno							y			
Intended Use: Diagno follows:	stic	ultr	aso	und in		or fluid fl	•	f the hum	an body as	i
Clinical Application	Α	В	M	PWD		Color Doppler	Power	Color Velocity Imaging	Combined	Tissue Harmonic Imaging
Opthalmic										
Fetal										
Abdominal		P	ρ	ρ		Р	Р		Note 1	P
OWGYN		Р	P	P		P	P		Note 1	P
IntraOperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)										
Neonatal Cephalic		_								
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal							•			
Conventional	<u> </u>	<u> </u>	<u> </u>			ļ				
Muscular-Skeletal										
Superficial Others (Specify)	├	-	-			<del> </del>		<del> </del>		
Others (Specify)  N = new indication P  Note I: Combined include  B/Power Dopple  Additional Comments	les: I r/PW	B/M;							Doppler/PWD	and
			Coo	MITTERIOR OF	CDRB. Of	ice of Device Ev	alustica (ODE)			-
							ancyc br			
Prescription Use (Per 21	CFR	801.	109)	I			produčtive, Abo at Qevices	JODANIC		
Section 4.3				In	dications	(For Use ich	K052	042	Page 5 of 10	0

510(k) Number:			-							
Device Name: MPTE Diagno	-						lti-Plane Tran	sesophag	jeal Phased	1 Array
Intended Use: Diagno follows:	ostic	ultı	asc	ound im	•	or fluid fl	•	f the hum	an body as	ì
Clinical Application	Α	В	М	PWD			Power	Color	Combined	Tissue
, ,						Doppler	(Amplitude) Doppler	Velocity Imaging		Harmonio Imaging
Opthalmic										
Fetal										1
Abdominal										
Ob/GYN										
IntraOperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)										
Neonatal Cephalic	L.									
Adult Cephalic										
Cardiac	<u> </u>									
Transesophageal		N	N	N	N	N	N		Note 1	N
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral Vascular		_								
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										
N = new indication P Note 1: Combined includ B/Power Dopple	ies: I	B/M;	•		•		idded under Ap 3/Power Doppler	•	Doppler/PWD	and
Additional Comments	<b>S</b> :									
			Con	currence of	CDRE, Of	ice of Device Ev	aleation (ODE)		_	-
Prescription Use (Per 21	CEB	201				(Division Division o	Maney	Abdoma	don al,	
1 1000 april Osc (Fel 21)	OI K	<del>0</del> 71,	103	,		O TO(K) NU	imber	520	342	<b>-</b> -· · · · ·

Section 4.3

Indications For Use

Page 6 of 10

510(k) Number:			-							
Device Name: 5P1, 7-							d Array			
Intended Use: Diagno follows:	stic	ultr	aso	und in		or fluid fl	•	of the hum	nan body as	3
Clinical Application	Α	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging		Tissue Harmonic Imaging
Opthalmic										
Fetal										
Abdominal										
Ob/GYN	П				T					
IntraOperative Neurological										
Pediatric		N	N	N	N	N	N		Note 1	N
Small Organ (breast, thyroid, testes)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N	N	N		Note 1	N
Transesophageal						<u> </u>				
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular			_							
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										
N = new indication P Note 1: Combined include B/Power Dopple Additional Comments	les; E r/PW	3/M;							Doppler/PWD	and
			Conc	MITTENDE OF	CDRIL OF	lice of Device Ev	sluctice (ODE)			-
					(D	vivision Sig	meye Gr	oglon		
Prescription Use (Per 21	CFR	<b>8</b> 01.	109)		U	AIRIOU OI H	eproductive A	bilominal,		
Section 4.3				In	ari	n uga(0)00	gical Devices per <b>Ko 5</b> 2		Page 7 of 1	0

510(k) Number:			-							
Device Name: C611, Diagno							cro-convex Ar	тау		
Intended Use: Diagnot follows:	stic	ultı	aso	und in		or fluid fl of Operation		f the hum	an body as	i
Clinical Application	Α	В	M	PWD	CWD		Power	Color Velocity Imaging	Combined	Tissue Harmonic Imaging
Opthalmic										
Fetal	$\Box$									
Abdominal	П									
Ob/GYN	$\Box$									
IntraOperative	$\Box$								-	
Neurological	1 1									
Pediatric	$\Box$	N	N	N	-	N	N		Note 1	N
Smali Organ (breast, thyroid, testes)										
Neonatal Cephalic	$\Box$									
Adult Cephalic										
Cardiac	$\Box$	N	N	N		N	N		Note 1	N
Transesophageal	1 1	$\vdash$								
Trans-Rectal	1					1				
Trans-Vaginal	$\Box$									
Trans-Urethral	$\Box$				1					
Intra-Vascular	1									
Peripheral Vascular	$\Box$		$\vdash$							
Laparascopic	1	$\vdash$	<del>                                     </del>			<u> </u>		İ	······································	
Muscular-Skeletal	1-	$\vdash$	-		1	<del> </del>				
Conventional	1 1		-		ł		1			
Muscular-Skeletal				1						
Superficial										
Others (Specify)										
N = new indication P Note 1: Combined include B/Power Dopple	des: B	3/M;					added under Ap 3/Power Doppler		Doppler/PWD	and
Additional Comments	3:									
			<u></u>		Chou M	fice of Device Ev	about a (OOF)			-
			-		CDR4 O	ince of severe se				
						· ·	7000	2		
Prescription Use (Per 21	CFR	<b>8</b> 01.	.109)	)	-		gn-Off) gn-Off) Reproductive, A gical Devices	Abdominal	n	Pro corre
Section 4.3				ln	dicatiogs	1586/Klum	ber <u>KO</u>	520	Page 8 of 10	) — -

510(k) Number:			_							
Device Name: 6V1, 8 Diagno							nsvaginal Mic	ro-convex	Array	
Intended Use: Diagnotollows:	stic	: ultı	raso	und in		or fluid fl	•	of the hum	an body as	<b>;</b>
Clinical Application	Α	В	M	PWD		Color Doppler	Power	Color Velocity Imaging	Combined	Tissue Harmonio Imaging
Opthalmic										
Fetal		Г								
Abdominal		Π								
Ob/GYN		N	N	N		N	N		Note 1	N
IntraOperative Neurological										
Pediatric	_	_				<u> </u>				
Small Organ (breast, thyroid, testes)										
Neonatal Cephalic		<u> </u>				<b> </b>				
Adult Cephalic		<u> </u>			ļ <u> </u>	<u> </u>				ļ
Cardiac										
Transesophageal		L.			<u> </u>	<u> </u>				
Trans-Rectal	_	N	N	N		N	N	1	Note 1	N
Trans-Vaginal	_	N	N	N		N	N		Note 1	N
Trans-Urethral							<u> </u>			
Intra-Vascular		_								
Peripheral Vascular		_								
Laparascopic						<u> </u>				
Muscular-Skeletal					1					
Conventional		<u>                                     </u>							<u> </u>	<u> </u>
Muscular-Skeletal										l
Superficial Others (Specify)		├-	-			ļ				<del> </del>
	les: E	B/M;					l added under Ap 3/Power Doppler		Doppler/PWD	) and
Additional Comments	:									
			Conc	errence of	CDRH, Of	ice of Device Ev	slustics (ODE)			_
					(D:	/	lancyc (	noado	n	
Prescription Use (Per 21 (	)FR	<b>8</b> 01.	109)		Divi	rision Sign ision of Re	POTOduotina AL	. 0 .		
Section 4.3				ln	dica (jong	F97Visinbe	cal Devices erKOS	204	Page 9 of 1	0 -

510(k) Number: K052042

Device Name: 10L1, 12-5MHz/38mm/128 element Flat Linear Array

Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as

follows:

Mode of Operation M PWD CWD Color Power Color Combined Tissue Clinical Application В Harmonic Doppler (Amplitude) Velocity **Imaging** Doppler **Imaging** Opthalmic **Fetal Abdominal** Ob/GYN **IntraOperative** Neurological Pediatric Small Organ (breast, N N N N N N Note 1 thyroid, testes) Neonatal Cephalic Adult Cephalic Cardiac Transesophageal Trans-Rectal Trans-Vaginal Trans-Urethral Intra-Vascular N Peripheral Vascular N N N N Note 1 N Laparascopic N Muscular-Skeletal N N N N Note 1 Conventional Muscular-Skeletal Superficial Others (Specify)

N = new indication P = previously cleared by FDA E = added under Appendix E Note 1: Combined includes: B/M; B/PWD; B/Color Doppler; B/Power Doppler; B/Color Doppler/PWD and B/Power Doppler/PWD Additional Comments: Concurrence of CDRH, Office of Device Evaluation (ODE) (Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

K052042 Revised Page 10 of 10 510(k) Number Indications For Use

Section 4.3

AUG 9 - 2005

# PREMARKET NOTIFICATION [510(k)] Summary

Trade Name:

SonoScape Ultrasound System, SSI-1000/SSI-5000™ with 6V1

Micro-convex EndoCavity Linear Array, 10L1 Linear Array, MPTEE

Multi-plane Trans-Esophageal Phased Array, 5P1 Phased Array, and

C611 Micro-Convex Linear Array transducers.

Common Name:

Diagnostic Ultrasound System and Transducers

Classification Names: Ultrasonic Pulsed Echo Imaging System, 90 IYO

Ultrasonic Pulsed Doppler Imaging System, 90 IYN

Diagnostic Ultrasound Transducer, 90 ITX

Manufacturer's Name: SonoScape Company Limited

4/F., Yizhe Building, Yuquan Road,

Nanshan, 518051, Shenzhen, China

Contact:

Mr. Jinzhong Yao, President

Telephone: (86) 755-26722890

Fax: (86) 755-26722850

U.S. Agent:

**Bob Leiker** 

Quality & Regulatory Services, Inc.

Dublin, CA 94568

**Predicate Devices:** 

SonoScape SSI-1000/SSI-5000, K042369 and the GE LogiQ 500,

K970901, K991611, and K010329

The SonoScape SSI-1000/SSI-5000 ultrasound system is an **Device Description:** integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications.

The all digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility and confidence provided by the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in depth soft-menu control allows the advanced user to set the system for different situations.

The SonoScape System can be configured either as a portable (SSI-1000) model, or as a roll-around model on wheels (SSI-5000).

Intended Use: The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen; Pediatric; Small Organ (breast, tests, thyroid); heart soft tissue; Peripheral Vascular, Musculo-skeletal (conventional) and Urology.

nological Cha Display Modes	Single and dual 2-D; Display of Duplex 2-D/M-mode; 2-D/Pulsed Doppler and Triplex 2-D/CD/Pulsed Doppler image formats; Dual B and Color in real time
	Implex 2-D/CD/Pulsed Doppler Image formats, Bull Bl. Cardiac OB and Vascular
Measurements	Distance; area; circumference; calipers; velocity, PI, RI. Cardiac. OB and Vascular
	package package
Principle of	Applying high voltage burst to the Piezoelectric material in the transducer and
Operation	detect the reflected echo to construct the 2-D B-mode, Doppler color, and Doppler
	spectrum image for diagnostic purpose.
Operating	TGC 8 slider, +/- 24dB
Controls	Depth Range: 3 to 24 cm
	Image sector size: 32 lines to full B (256 lines)
	Image Sector position: Steering within full maximum
	B orientation flip: L/R key with marking on the screen
	B Dynamic range control: preset 5 curves over 50-90 dB
	Gray Scale Control: 8 Settings
	Focal Number: 16 focal zone setting
	B persistence: 30-90% recursive
	Image Processing: Smoothing, edge enhancement
	PW sweeping speed 2,4,8 sec over display.
	PW Wall filter setting: 16 settings, 0.25 to 20% of PRF
	PW sample volume: 0.5 to 10mm with 0.5mm step size.
	PW/B update: with UPDATE key
	PW cursor steering: Steer soft key
	PW angle correction: 0 to 70 degree user control
	PW trace: Peak, Mean
	DIAL an activity displaying range; 5 present curve over 15-48 dB
	On a drawn becaling shift and invert
	Out - DOL - Wine trackhall and set key to control size and position
	Out and a single and flot probes 4. O
	A Live William Color well filter with 16 colortion 0.25-20% of PRE
	Color Wall Filter: Color Wall filter with To selection, 0.23-20 % 0.7 T.      Color & B priority: C-B priority soft menu
	Only Deplot size proper per Even range from 8 to 12
	Color Packet size: preset per Exam range from 8 to 12
	Color spatial filter: preset per Exam, horizontal, vertical, off
	Zoom factor: 1 to 10 continuously
	Cine control: step, play backward, play continuously
Acoustic	Track 3; MI, TIS, TIC, TIB
Output	Derated Ispta: 720mW/cm2 maximum, TIS/TIB/TIC:0.1-4.0 Range, Mechanical
	Index: 1.9 Maximum, or Derated Isppa: 190 W/cm² max
Display	Time/date/year; transducer type; power output in %; frames per second; persistence; and compression settings; image depth; patient name and ID;
Annotations	institution name; focal position; TGC curve display; Doppler & M scale in sec;
	institution name; tocal position, TGC curve display, poppler a tri socie in cost,
	Doppler angle correction cursor; EKG trace; probe tip temperature / angle for MPTEE; free form annotation anywhere on image; trackball controlled; selective
	global erase of the display annotations, body markers with transducer annotation
	IEC601-1 International Electrotechnical Comission; Medical Electrical Equipmen
Safety	IEC601-1 International Electrotechnical Comission; Medical Electrotechnical Comission; Electromagnetic
Compliance	
	Compatibility